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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,422	02/03/2000	Stephen A. Berry	ARC2914 US R1 (3139-6169U)	7482
7590		10/28/2004	EXAMINER	
Edgar R. Cataxinos		FUBARA, BLESSING M		
TraskBritt, PC		ART UNIT		
PO Box 2550		PAPER NUMBER		
Salt Lake City, UT 84110		1615		

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/497,422

Applicant(s)

BERRY ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,15-18,21-23,27,29-32,34-38,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11,15-18,21-23,27,29-32,34-38,46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 08/09/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of IDS, amendment and remarks filed 08/09/04. Claims

1, 11, 15-18, 21-23, 27, 29-32, 34-38, 46 and 47 are pending.

1. The indicated allowability of claims 10 and 11 is withdrawn in view of improper language in the claims and in view of the rejections that follow.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 10, 11, 15-18, 21-23, 27, 29-32, 34-38, 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 11, 15, 16, 29 and 35 are of improper Markush under 35 USC 112.

Claims 10, 11, 15, 16, 29 and 35 are indefinite because the claims are vague and ambiguous. The claims require at least three components but the claims further require the selection of the three components from the group consisting of ... according to Markush language claims. However, the Markush language requires that one component be selected from the listing; and thus it is ambiguous if the vehicle contains three components or the vehicle contains one of the elements in the Markush group.

Therefore, in light of the Markush group, the generic claims are interpreted as comprising polyvinylpyrrolidone, glycerol monolaurate or lauryl lactate. The viscosity of the vehicle is not accorded patentable weight to the vehicle because the generic claims are broad vehicle claims

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that contain polyvinylpyrrolidone, polysorbate or glycerol monolaurate, or lauryl lactate and a vehicle that comprises the recited component would inherently possess that viscosity. Absent a showing, the recited viscosity has no critical significance to a vehicle that comprises polyvinylpyrrolidone, polysorbate or glycerol monolaurate, or lauryl lactate.

Claim 15 is unclear because line 3 recites “two components” and line 7 recites “three components.”

Claim 16 is unclear because line 6 recites “two components” and line 9 recites “three components.”

Claim 34 depends of claim 35. A dependent claim depends on previous claim and not on a succeeding claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 10, 11, 15-17, 21-23, 27, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Daher et al. (US 4,376,118).

Daher discloses a non-aqueous solution that comprises a mixture of tetracycline antibiotic salt, non-aqueous diluent, non-aqueous solvent, non-aqueous non-ionic solubilizer, antioxidant and non-aqueous anionic solubilizer (abstract). Lauryl lactate is a diluent (column 1, line 58),

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polysorbates, ethylene oxide propylene oxide block copolymers are non-aqueous solubilizers (column 2, lines 6-12), and ethanol or methanol or N-methyl-pyrrolidone are solvents (column 1, lines 51-53). The tetracycline beneficial agent is present in amounts of 0.25 to 2% (column 2, lines 26-52). The method claims administer the generic composition as recited in generic claims and antibiotics are expected to be administered to a subject in need thereof. The viscosity of a composition is necessarily a function of the composition and the viscosity is not accorded any patentable weight. In the absence of a showing, the recited viscosity is not critical to a vehicle/product/composition that comprises either polyvinylpyrrolidone, polysorbate or glycerol monolaurate, or lauryl lactate. There is no demonstration in applicants' disclosure that a composition prepared with a beneficial agent having been dried to a low moisture content conveys special properties to one that is formed with a beneficial agent that has not gone through drying or desiccation process. The Markush claim language requires that the composition contain a component that is selected from solvent, polymer and surfactant; and by the Markush, polymer or surfactant or solvent containing vehicle of the prior art meets the limitation. The "comprises" allows for the presence of components other than the recited components. Thus Daher anticipates the claims.

6. Claims 10, 11, 15, 16, 46 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Lyle (US 5,814,323).

Lyle discloses cosmetic composition that comprises glycerol monolaurate amphiphilic material (column 2, line 28), lauryl lactate or glycerol monoether non-ionic surfactant (column 5, lines 19 and 29) and a polyvinylpyrrolidone thickener (column 6, line 48). Regarding the recited viscosity, there is no demonstration that the recited viscosity affords unusual properties to

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the instant vehicle; and in the absence of a showing the viscosity is not critical to a composition that comprises lauryl lactate or glycerol monolaurate. The viscosity of a composition is necessarily a function of the composition and the viscosity is not accorded any patentable weight. In the absence of a showing, the recited viscosity is not critical to a vehicle/product/composition that comprises either polyvinylpyrrolidone, polysorbate or glycerol monolaurate, or lauryl lactate. There is no demonstration in applicants' disclosure that a composition prepared with a beneficial agent having been dried to a low moisture content conveys special properties to one that is formed with a beneficial agent that has not gone through drying or desiccation process. The Markush claim language requires that the composition contain a component that is selected from solvent, polymer and surfactant; and by the Markush, polymer or surfactant or solvent containing vehicle of the prior art meets the limitation. The "comprises" allows for the presence of components other than the recited components. Lyle anticipates the claims.

7. Claims 10, 11, 15-18, 21-23, 27, 34, 35, 46 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Farinas et al. (US 5,928,666).

Farinas discloses a composition that comprises polyvinylpyrrolidone (column 6, line 50), glycerol monolaurate or lauryl lactate (column 7, lines 18 and 19). Estradiol beneficial agent is present in amount of 20 weight% in Example 3. The viscosity of a composition is necessarily a function of the composition and the viscosity is not accorded any patentable weight. In the absence of a showing, the recited viscosity is not critical to a vehicle/product/composition that comprises either polyvinylpyrrolidone, polysorbate or glycerol monolaurate, or lauryl lactate. There is no demonstration in applicants' disclosure that a composition prepared with a beneficial

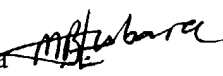
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agent having been dried to a low moisture content conveys special properties to one that is formed with a beneficial agent that has not gone through drying or desiccation process. The Markush claim language requires that the composition contain a component that is selected from solvent, polymer and surfactant; and by the Markush, polymer or surfactant or solvent containing vehicle of the prior art meets the limitation. The "comprises" allows for the presence of components other than the recited components. Farinas meets the limitations of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara 
Patent Examiner
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